

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

***APPLICATION NUMBER:***

**85035**

**CHEMISTRY REVIEW(S)**

OR SUPPLEMENT

AF Number 85-035

Name and Address of Applicant (City and State)

generic pharmaceutical corp  
palisades park, NJ 07650

Original	_____
Amendment	_____
Supplement	_____
Resubmission	_____
Correspondance	_____
Report	_____
Other	_____

Purpose of Amendment/Supplement

orig abbr NDA

Date(s) of Submission(s)

11/12/78

Pharmacological Category

antiperistaltic

Name of Drug

diphenoxylate HCl +  
atropine SO4

Dosage Form(s)

oral

Potency(ies)

2.5 + 0.025 mqs  
respectively

How Dispensed

Rx xxx

OTC

Packaging/Sterilization

submitted

Samples

requested

Related IND/NDA/MF

Labeling

as per MO(vvkaruaitis)

Biologic Availability

NA

Establishment Inspection

requested

Components, Composition, Manufacturing and Controls

as per letter to issue

Remarks

rev w/f

gmillar

ca 11/12/78

Conclusion

Reviewer

DATE

AF Number

Name and Address of Applicant (City and State)

generic pharmaceutical corp.  
palisades park. NJ 07650

Original

Amendment

Supplement

Resubmission

Correspondance

Report

Other

Purpose of Amendment/Supplement

amend

Date(s) of Submission(s)

5/27/77

Pharmacological Category

antiperistaltic

Name of Drug

diphenoxylate HCL \_ atropine SO4

Dosage Form(s)

oral

Potency(ies)

~~2x5~~ 2.5/0.025 mg

How Dispensed

Rx xxx

OTC

Packaging/Sterilization

submitted

Samples

validated by NY-DO as per 5/2/77  
review

Related IND/IDA/IF

Labeling

as per MO(vvkarusatis)  
containers additionally bear JDAVIS name

Biologic Availability

MC-deferred

Establishment Inspection

in compliance as per HFD-322 memo of 2/15/77

Components, Composition, Manufacturing and Controls

satisfactory

NB: proposed dissolution procedure = extr quality control

Remarks

approved

gmillar

April 24/77

Conclusion

REV. USER

DATE